K021109
page 1 of 2

JUN 12 2002

510 (K) SUMMARY – Metallic Femoral Head

Submitter name:	Fournitures Hospitalières Industrie
Submitter adress:	6 Rue Nobel, Z.I. de Kernevez QUIMPER, France 29000
Contact person:	Mrs Christine QUENDEZ
Phone Number: **Fax Number:**	+33.2.98.55.68.95 +33.2.98.53.42.13
Date prepared:	April 5, 2002
Device Trade Name:	Metallic Femoral Head
Device common name:	Femoral head
Classification name:	Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Predicate Device:	Headloc™ Femoral Head Primaloc® Cementless Hip System (K953977) Ortho Development Corporation Intrinsic® Cementless Total Hip System (K923911) Ortho Max. Inc. Exactech AcuMatch Hip System (K010081)
Device description:	The Metallic Femoral Heads are intended to be adapted to special cones machined for this purpose. Femoral head are available in several diameter for use in full hip or intermediary replacement. The length of the neck on the femoral stem can be adjusted by using the heads available in different insertion depths (short, medium, long and extra-long collars), and of different diameter.
Intended use:	Prosthetic replacement of the femoral head associated with hip prosthesis, which cone is compatible with the head's cone and with a prosthetic acetabular cup, whose diameter is compatible with the head.

Device Technological

K021109
page 2 of 2

Characteristics and Comparison to Predicate Devices:

Femoral heads made of chrome cobalt (∅ 28 & 32 mm), short collar, medium collar long collar & extra-long collar with cone dimensions 12/14, 5°43' & 10/12, 6°. The identified predicate devices have the same intended use, are made of the same material, have the same size, and collar + cone dimensions are of the same order of magnitude.

Performance Data:

Testings conducted to characterize the materials under defined laboratory conditions are provided to support a finding of substantial equivalence.

Conclusion:

The Metallic Femoral Heads are substantially equivalent to predicate devices in terms of intended use, safety, and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 12 2002

Fournitures Hospitalières Industrie
c/o Dr. Andre Weith
Director, Pro-Active Healthcare
c/o PharmaNet, Inc.
815 Connecticut Avenue NW, Suite 800
Washington, D.C. 20006

Re: K021109
Trade/Device Name: ESOP® Co-Cr Femoral Heads
Regulation Number: 21 CFR 888.3358
Regulation Name: Hip joint metal/polymer/metal semi-constrained porous-coated uncemented prosthesis
Regulatory Class: II
Product Code: LPH
Dated: April 5, 2002
Received: April 5, 2002

Dear Dr. Weith:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K021109 page 1 of 1

Device Name: ESOP® Co-Cr Femoral Heads

Indications for Use:

The ESOP® Co-Cr Femoral Heads are intended for use in degenerative and inflammatory arthritis of the hip joint, trauma, non-acute femoral neck fracture, revision of previously failed hip arthroplasties, and idiopathic avascular (osteo) necrosis where radiographic evidence shows there is sufficient sound bone to seat the prosthesis. This device is intended for cementless application.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH; Office of Device Evaluation (ODE)

for Mark N Milhern

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021109

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

(Optional Format 1-2-96)